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IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA

JOHN and JANE DOE 2, Individually
and as Guardians Ad Litem of
MINOR CHILD DOE 2,

Plaintiffs,

v.

ORTHO-CLINICAL DIAGNOSTICS,
INC. and ELI LILLY & COMPANY,

Defendants.

1:03CV00669

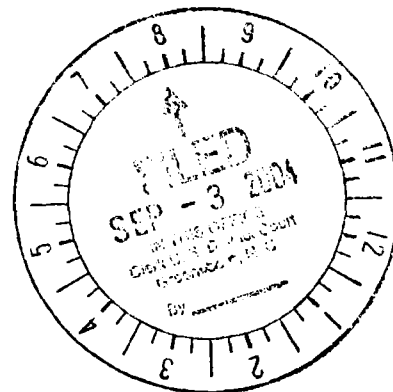
MEMORANDUM OPINION

BEATY, District Judge.

I. INTRODUCTION

This matter comes before the Court on Defendant Eli Lilly & Company's ("Eli Lilly") Motion to Dismiss¹ [Document #1, Ex. 18] and Defendant Ortho-Clinical Diagnostics, Inc.'s ("Ortho-Clinical") Motion to Dismiss, or in the Alternative, Motion to Stay [Document #11] ("Motion to Dismiss or Stay") claims filed by Plaintiffs John and Jane Doe 2, Individually and as Guardians Ad Litem of Minor Child Doe 2 ("Plaintiffs"). Plaintiffs filed their Complaint [Document #1, Ex. 1] against Defendants alleging various state-law claims related to Eli Lilly's alleged production and marketing of the drug thimerosal and Ortho-Clinical's production of the immune globin product RhoGAM (which contains thimerosal). Both Eli Lilly and Ortho-Clinical move this Court to dismiss Plaintiffs' claims pursuant to Federal Rule of Civil Procedure 12(b)(1),

¹ The Court notes that Eli Lilly's Motion to Dismiss was originally filed in state court. In conjunction with this Motion to Dismiss, Eli Lilly also filed in state court a Motion for Change of Venue. As this matter has been subsequently removed to this Court and neither Defendant has contested the propriety of venue in this Court, the Court finds Eli Lilly's original Motion for Change of Venue to be moot.



asserting that this Court lacks jurisdiction over these claims under the National Childhood Vaccine Injury Compensation Act (the “Vaccine Act”), 42 U.S.C. §§ 300aa-1 to 300aa-34. Both Defendants also move this Court to dismiss Plaintiffs’ claims pursuant to Rule 12(b)(7) for failure to join indispensable parties. Eli Lilly also moves this Court to dismiss Plaintiffs’ claims pursuant to Rule 12(b)(6).² Both Defendants also move, in the alternative, for this Court to stay the proceedings in this matter during the pendency of Plaintiffs’ petition in Vaccine Court.

II. FACTUAL BACKGROUND AND PROCEDURAL HISTORY

Plaintiffs allege that Minor Child Doe 2 (“Minor Child Doe”) has suffered severe neurodevelopmental disorders and permanent injuries from exposure to toxic levels of mercury. Plaintiffs claim that this mercury exposure resulted from shots of RhoGAM that Jane Doe received while pregnant with Minor Child Doe. Plaintiffs also allege that Jane Doe received a RhoGAM injection after giving birth to Minor Child Doe, and Minor Child Doe was thereafter re-exposed to mercury through breast milk. RhoGAM, which is manufactured by Defendant Ortho-Clinical, is administered to Rh-negative mothers and their unborn children to prevent blood incompatibility between mother and child. Plaintiffs allege that the RhoGAM administered to Plaintiff Jane Doe contained a preservative known as thimerosal, which contains toxic levels of mercury. (*Id.*) Plaintiffs further allege that Defendant Eli Lilly designed and/or held a design patent for thimerosal, actively marketed thimerosal, manufactured thimerosal, licensed thimerosal to other manufacturers, and, when its patent expired, knew that other manufacturers were copying its design.

² Eli Lilly moves in the alternative for summary judgment pursuant to Federal Rule of Civil Procedure 56. The Court finds it appropriate, however, to resolve Eli Lilly’s Motion under Rule 12(b)(6). The Court therefore will not further address Eli Lilly’s alternative request for summary judgment.

Plaintiffs further contend that the thimerosal-related injuries caused by the RhoGAM were significantly aggravated when Minor Child Doe received vaccines that also contained thimerosal. As discussed more fully below, however, the Vaccine Act prohibits Minor Child Doe (through her parents) from bringing her significant-aggravation claims against the vaccine manufacturers in this Court until she has exhausted her administrative remedies in Vaccine Court. Minor Child Doe is therefore currently pursuing her significant-aggravation claims in a related proceeding in Vaccine Court.

Plaintiffs originally filed their claims against Ortho-Clinical and Eli Lilly (as well as other defendants, who were dismissed in state court) in the General Court of Justice, Superior Court Division, Durham, North Carolina. The matter was removed to this Court on July 15, 2003, on the basis of diversity jurisdiction under 28 U.S.C. § 1332. (Notice Removal [Doc. #1].) Defendant Eli Lilly had previously filed a Motion to Dismiss in state court, which is now pending before this Court. Defendant Ortho-Clinical filed its Motion to Dismiss and/or Stay on January 2, 2004. All parties have filed their respective briefs on this matter, and the Court held a hearing on the pending Motions on March 17, 2004. The Court therefore finds Defendants' Motions to be ripe for adjudication.

III. DISCUSSION

In their Complaint, Plaintiffs assert various claims against Eli Lilly and Ortho-Clinical. Plaintiffs' Complaint is divided into four sections. Section A includes the claims Plaintiffs bring solely against the "Product Defendants." Included in Section A of the Complaint is Ortho-Clinical, because it is alleged to have produced the RhoGAM that was administered to Jane Doe. (Compl. ¶ 48.) Also apparently included in Section A is Eli Lilly, because Plaintiffs originally contended that

Eli manufactured the thimerosal contained in the RhoGAM administered to Jane Doe. (Compl. ¶ 49.) Plaintiffs assert the following claims against the Product Defendants (including Ortho-Clinical and Eli Lilly): (1) negligence, (2) negligent failure to warn, (3) inadequate design or formulation, (4) breach of express warranty of merchantability, (5) breach of implied warranties, (6) negligent misrepresentation, (7) intentional misrepresentation and fraud, and (8) violation of the North Carolina Unfair and Deceptive Trade Practices Act.

Section B originally included claims against the “Medical Distributor Defendants.” These defendants, however, were dismissed in state court. Section B of the Complaint is therefore no longer relevant to this litigation. Section C includes a claim solely against Eli Lilly for “negligence in the marketing, licensing and design of Thimerosal.” Finally, Section D is asserted against “All Defendants,” who now include just Ortho-Clinical and Eli Lilly. In this section of the Complaint, Plaintiffs assert four additional claims against Ortho-Clinical and Eli Lilly: (1) negligent infliction of emotional distress, (2) gross negligence, (3) punitive damages, and (4) loss of parental consortium.

Both Eli Lilly and Ortho-Clinical move this Court to dismiss Plaintiffs’ claims pursuant to Federal Rule of Civil Procedure 12(b)(1), asserting that this Court lacks jurisdiction over these claims under the Vaccine Act. Both Defendants also move this Court to dismiss Plaintiffs’ claims pursuant to Rule 12(b)(7), asserting that Plaintiffs have failed to join indispensable parties to this action. Defendant Eli Lilly further contends that it is entitled to dismissal of Plaintiffs’ claims against it pursuant to Rule 12(b)(6) because it did not manufacture the thimerosal contained in the RhoGAM administered to Minor Child Doe. In the alternative, both Defendants request this Court to stay these proceedings during the pendency of Plaintiffs’ claims in the Vaccine Court.

The Court will first discuss Defendants’ Motions to Dismiss pursuant to Rule 12(b)(1). The

Court will then discuss Eli Lilly's Motion to Dismiss pursuant to Rule 12(b)(6). The Court will then discuss the Rule 12(b)(7) Motion asserted by Ortho-Clinical. Finally, the Court will discuss Ortho-Clinical's alternative Motion to Stay.

A. Defendants' Motions to Dismiss Pursuant to Rule 12(b)(1)

Both Defendants assert that the Vaccine Act requires this Court to dismiss all claims against them because Plaintiffs allege "vaccine-related" injury claims that the Vaccine Act requires to be first adjudicated in Vaccine Court. Plaintiffs contend, however, that the Vaccine Act does not apply to this case because Defendants are not vaccine administrators or manufacturers. As this Court has recently held in Laughter v. Aventis Pasteur, Inc., 291 F. Supp. 2d 406 (M.D.N.C. 2003), the Vaccine Act sets forth a scheme for compensation for vaccine-related injuries or death. 42 U.S.C. § 300aa-15. Under the Vaccine Act, a vaccine-related injury is defined as "an illness, injury, condition, or death associated with" a vaccine identified in the Act. Id. § 300aa-33(5). Congress enacted the Vaccine Act to create "a scheme of recovery designed to work faster and with greater ease than the civil tort system." Shalala v. Whitecotton, 514 U.S. 268, 269, 115 S. Ct. 1477, 1478, 131 L. Ed. 2d 374 (1995). The Vaccine Act established the National Vaccine Injury Compensation Program, which is designed to "ensure that all children who are injured by vaccines have access to sufficient compensation for their injuries." H.R. Rep. 99-908, at 5 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6346. The Vaccine Act is further designed "to free manufacturers from the specter of large, uncertain tort liability, and thereby keep vaccine prices fairly low and keep manufacturers in the market." Schafer v. Am. Cyanamid Co., 20 F.3d 1, 4 (1st Cir. 1994).

The Vaccine Act requires that all claims against a vaccine administrator or manufacturer alleging a "vaccine-related injury" be brought initially in the Court of Federal Claims, whereupon

they are assigned to a special master familiar with Vaccine Act claims. 42 U.S.C. §§ 300aa-11(a)(1), -11(a)(2)(A), -12(d). Section 11(a)(2)(A) of the Act provides that

[n]o person may bring a civil action for damages . . . against a *vaccine administrator or manufacturer* in a State or Federal court for damages arising from a vaccine-related injury or death associated with the administration of a vaccine . . . unless a petition has been filed, in accordance with section 300aa-16 of this title, for compensation under the Program for such injury

Id. § 300aa-11(a)(2)(A) (emphasis added). The Act directs an individual who is injured by a vaccine to file a petition with the Court of Federal Claims against the United States Government rather than against the vaccine manufacturers or the doctors who administered the vaccines. After a judgment has been entered by a special master in the Vaccine Court, the petitioner may elect either to accept the judgment or to file a civil action for damages in state or federal court. Id. § 300aa-21(a). Alternatively, if the special master does not make a decision on the petition within 240 days, the petitioner may withdraw the petition from the Vaccine Court and file a civil action in federal or state court. Id. § 300aa-21(b)(1).

Thus, the Vaccine Act prevents an individual or someone acting on behalf of the individual from filing a separate civil action against a vaccine administrator or a vaccine manufacturer without either (1) obtaining a judgment from the Vaccine Court and electing to file a civil action or (2) withdrawing the petition from the Vaccine Court pursuant to § 21(b). Id. § 300aa-11(a)(2)(A). The Court of Federal Claims, citing § 11(a)(2)(B) and § 11(a)(3), has construed the Act to require that

if the vaccinee misinterprets or ignores the Court of Federal Claims's jurisdiction over claims brought pursuant to the Vaccine Act, and instead, for whatever reason, files a civil action in state or federal court, *the state or federal court must dismiss the claim* until the vaccinee exhausts her remedies under the Program.

Leroy v. Sec'y of the Dep't of Health & Human Servs., No. 02-392V, 2002 WL 31730680, at *3 (Fed. Cl. Oct. 11, 2002) (emphasis added).

Defendants argue that Plaintiffs' present civil action in this Court violates the Vaccine Act's requirement that plaintiffs exhaust their remedies in Vaccine Court before filing a civil action in state or federal court. Defendants advance two interrelated arguments in support of this assertion. First, Defendants argue that Plaintiffs are attempting to recover for the same injuries in this Court as they are in Vaccine Court. Second, Defendants argue that because Minor Child Doe's injuries from RhoGAM are vaccine-related, Minor Child Doe must first exhaust her administrative remedies in Vaccine Court prior to proceeding with her claims against Ortho-Clinical and Eli Lilly in this Court. The Court will address Defendants' arguments in turn.

1. Whether Plaintiffs Are Seeking the Same Relief in Vaccine Court as They Are in This Court

Defendants argue that dismissal is appropriate because Plaintiffs are "attempt[ing] to proceed in two courts against different defendants for the same injury which plaintiffs themselves attribute in both actions to thimerosal." (Reply Br. Supp. Ortho-Clinical's Mot. Dismiss or Stay [Doc. #16].) Plaintiffs, however, assert that they are not bringing the same claims in this Court as they are in Vaccine Court. Plaintiffs contend that in this Court they assert that the thimerosal in RhoGAM *caused* Minor Child Doe's neurological disorders. Plaintiffs contend that in Vaccine Court they are asserting that thimerosal contained in vaccines *significantly aggravated* Minor Child Doe's pre-existing neurodevelopmental disorder, which Plaintiffs alleged was initially caused by the RhoGAM. Plaintiffs are thus pursuing a significant aggravation claim in Vaccine Court. The Vaccine Act recognizes claims for significant aggravation, DeRoche v. Secretary of the Department of Health & Human Services, No. 97-643V, 2002 WL 603087 (Fed. Cl. Mar. 28, 2002), and the Act defines significant aggravation as "any change for the worse in a preexisting condition which results in markedly greater disability, pain, or illness accompanied by substantial deterioration of health." 42

U.S.C. § 300aa-33(4).

Defendants contend, however, that the petition Plaintiffs filed in the Vaccine Court demonstrates that Plaintiffs are actually claiming in Vaccine Court that the thimerosal in the vaccines *caused* (as opposed to significantly aggravated) Minor Child Doe's neurological disorders. Thus, Defendants contend that Plaintiffs are actually seeking the same relief both in Vaccine Court and in this Court. In support of this contention, Ortho-Clinical notes that the Vaccine Court, by Order dated July 3, 2002, stated that "any petitioner desiring that his or her Vaccine Act claim be processed along with the other 'Omnibus Autism' cases may file a 'Short-Form Autism Petition for Vaccine Compensation' similar to that contained at Ex. B to the Autism General Order #1." (Master Autism Petition for Vaccine Compensation [Doc. #12] at 1.) Ortho-Clinical further notes that in the Master Autism Petition for Vaccine Compensation ("Master Petition") the Vaccine Court stated, in pertinent part, that "[a]ny petitioner who files such a short-form petition will be deemed to be representing that such petitioner's own particular claim meets [certain] criteria":

3. As a direct result of one or more vaccinations covered under the National Vaccine Injury Compensation Program, the vaccinee in question has developed a neurodevelopmental disorder, consisting of an Autism Spectrum Disorder or a similar disorder. This disorder was *caused* by a measles-mumps-rubella (MMR) vaccination; by the "thimerosal" ingredient in certain Diphtheria-Tetanus-Pertussis (DTP), Diphtheria-Tetanus-acellular Pertussis (DTaP), Hepatitis B, and Hemophilus Influenza Type B (HIB) vaccinations; or by some combination of the two.

(Master Petition at 1–2 (emphasis added).)

Thus, Defendants contend that because Plaintiffs have represented in their short-form petition to the Vaccine Court that Minor Child Doe's injuries were *caused* by vaccines, it is clear that Plaintiffs are actually seeking the same relief against the United States Government in Vaccine Court that they are seeking against Ortho-Clinical and Eli Lilly in this Court. Defendants fail to

acknowledge, however, that the Master Petition also listed the following as one of the additional criteria that a petitioner would be representing:

5. The petition is being filed within three years after the first symptom of the disorder, or within three years after the first symptom of a vaccine-caused *significant aggravation* of the disorder. . . .

(Master Petition at 2 (emphasis added).) Thus, it is clear that the short-form petition encompasses both claims that the vaccine *caused* the injury or *significantly aggravated* the injury.

Accordingly, Ortho-Clinical has offered no evidence that Plaintiffs are seeking the same relief in Vaccine Court that they are seeking in this Court. The Court construes Plaintiffs' Complaint and their pleadings to assert that they are alleging that the thimerosal in RhoGAM was the initial cause of Minor Child Doe's neurodevelopmental disorder and the thimerosal in the vaccines Minor Child Doe later received significantly aggravated that disorder. Thus, Defendants' contention that Plaintiffs are seeking a double recovery by proceeding both in this Court and in Vaccine Court is without merit.

2. Whether Plaintiffs' Claims Against Eli Lilly and Ortho-Clinical Must Be Dismissed Because They are Vaccine-Related

Defendants further contend, however, that because Plaintiffs' claims against Ortho-Clinical and Eli Lilly are "vaccine-related," this Court lacks jurisdiction over Plaintiffs' claims. In support of this argument, Defendants argue that "courts across the country have concluded that [such a case] should be either dismissed or stayed, pending resolution of the Vaccine Court proceedings." (Mem. Supp. Ortho-Clinical's Mot. Dismiss and/or Stay [Doc. #12] at 8.) Defendants contend that the decisions in Agbebaku v. Sigma Aldrich, Inc., No. 23-C-02-004243, slip op. (Md. Cir. Ct. June 19, 2003), cert. denied, 844 A.2d 427 (Md. 2004), and Liu v. Aventis Pasteur, Inc., 219 F. Supp. 2d 762, 767 (W.D. Tex. 2002), support their position that this Court lacks jurisdiction over Plaintiffs' claims

against Defendants.

Liu, however, does not support Defendants' contention that this Court *must* dismiss Plaintiffs' claims as being barred by the Vaccine Act. In Liu, the plaintiffs sued both the vaccine manufacturers and the non-vaccine manufacturers for thimerosal-related injuries. The district court found that the minor child's claims against the vaccine manufacturers were barred by the Vaccine Act because the child had not exhausted his administrative remedies in Vaccine Court. With respect to the non-vaccine defendants, however, the district court found that the minor child's claims against the non-vaccine defendants were not barred by the Vaccine Act. The Court nevertheless dismissed the minor child's claims against these defendants without prejudice, finding that it would be inappropriate to allow discovery against the non-vaccine defendants while the same issues were pending against the vaccine defendants in Vaccine Court. The court noted that, under Texas law, the minor child would be able to refile his claims against these defendants after the conclusion of the proceedings in the Vaccine Court because the statute of limitations would not begin to run on these claims until he reached the age of majority. Thus, the district court in Liu dismissed the claims in the interest of judicial economy, not because dismissal was required by the Vaccine Act.

Defendants therefore rely primarily upon the Maryland state court case of Agbebaku to support their position that the Vaccine Act requires dismissal of Plaintiffs' claims. In Agbebaku, the plaintiffs, as in the present case, alleged that exposure to thimerosal caused neurological disorders in several minor children. The plaintiffs, claiming that the children were exposed to thimerosal both in vaccines and as a result of RhoGAM their mothers had received, sued various vaccine manufacturers as well as Ortho-Clinical, the manufacturer of RhoGAM. Ortho-Clinical, as in the present case, moved for dismissal on the grounds that the Vaccine Act barred the plaintiffs'

claims against it, even though RhoGAM is not a vaccine. The state court, finding that the plaintiffs' injuries from the RhoGAM were vaccine-related, dismissed Ortho-Clinical from the case.

The more persuasive federal authority, however, is contrary to the holding reached by the state court in Agbebaku. In Easter v. Aventis Pasteur, Inc., No. 5:03-CV-141, slip op. (E.D. Tex. Feb. 11, 2004), recons. denied, No. 5:03-CV-141, slip ops. (E.D. Tex. May 18, 2004), the Eastern District of Texas came to a different result than the one reached in Agbebaku. Easter involved precisely the same question before this Court: whether a claim against a manufacturer of RhoGAM (or a RhoGAM constituent) alleging a thimerosal-related injury is barred by the Vaccine Act. The district court answered this question in the negative, holding that it had jurisdiction over such a claim. The court specifically disavowed the holding in Agbebaku, noting that "the Agbebaku court ignored the issue of whether the globulin manufacturer in that case was a 'vaccine administrator or manufacturer' as defined under the Act." Easter, slip. op. at 13. The Easter court instead relied upon Toussaint v. Merck & Co., No. Civ.A. 02-3411, 2003 WL 21406178 (E.D. La. June 12, 2003), in which the Eastern District of Louisiana held that the Vaccine Act's provisions did not apply to non-vaccine manufacturers. Id. at *2.

Defendants further direct this court to two rulings by United States District Judge Louise Flanagan in the Eastern District of North Carolina in Doe 3 v. Ortho-Clinical Diagnostics, Inc., No. 7:03-CV-138-FL(1), slip op. (E.D.N.C. Jan. 7, 2004), recons. denied, No. 7:03-CV-138-FL(1), slip op. (E.D.N.C. Mar. 17, 2004). The Court notes that Doe 3 is factually identical to the case presently before this Court. Doe 3 involves the same defendants (Ortho-Clinical and Eli Lilly), the same attorneys, and virtually the same pleadings and briefs. In Doe 3, Judge Flanagan stayed the proceedings against both Ortho-Clinical and Eli Lilly pending the outcome of the Vaccine Court's

proceedings. She did not, however, dismiss Plaintiffs' claims against Ortho-Clinical or Eli Lilly as being barred by the Vaccine Act. In fact, although Judge Flanagan did not specifically decide the issue of jurisdiction in her opinions, it is clear from her opinions that she retained jurisdiction over the plaintiffs' claims. Thus, Judge Flanagan's rulings offer no support for Defendants' contentions that Plaintiffs' claims are barred by the Vaccine Act.

Defendants further contend, however, that “[s]hould Plaintiffs receive any compensation in this forum from any party for causing or contributing to Plaintiffs’ alleged injuries, the Vaccine Court has said that they would be forever barred from receiving any compensation in [the Vaccine Court] for the same injury.” (Br. Supp. Eli Lilly’s Mot. Dismiss [Doc. #3] at 5.) In support of this statement, Defendants cite Massing v. Secretary of the Department of Health & Human Services, 926 F.2d 1133, 1135 (Fed. Cir. 1991), in which the Federal Circuit dismissed the claimants’ Vaccine Court petition because the claimants’ petition did not comply with the requirements of 42 U.S.C. § 300aa-11(c), which governs the content of petitions filed with the Vaccine Court. Subsection 11(c)(1)(E) specifically requires a petitioner to provide an affidavit stating that he “has not previously collected an award or settlement of a civil action for damages for such vaccine-related injury or death. . . .” In Massing, the claimants had, prior to the effective date of the Vaccine Act, collected a vaccine-related settlement against doctors who were neither vaccine administrators nor manufacturers. After the Vaccine Act was enacted, the claimants filed a petition for compensation with the Vaccine Court. The special master (affirmed by the Federal Circuit) dismissed the claimants’ petition because the claimants had previously collected a vaccine-related settlement. The Federal Circuit noted that § 11(c)(1)(E)’s requirement that the claimant had not previously collected a vaccine-related settlement was not limited to settlements from vaccine administrators or

manufacturers; thus, the claimants' petition was improper and was dismissed.

Defendants' reliance on Massing, however, is misplaced. In fact, the district court in Easter, citing post-Massing precedent, specifically rejected an identical argument made by the defendants in that case. Easter, slip op. at 14. The Easter court relied in part upon the Federal Circuit's decision in Schumacher v. Secretary of the Department of Health & Human Services, 2 F.3d 1128 (Fed. Cir. 1993). In Schumacher, the Federal Circuit distinguished the Massing holding, noting that in Massing "[t]he court stated that the petitioner was 'attempting to construe the statute contrary to its plain meaning, and in order to do so, must show clear legislative history supporting its asserted construction. Petitioner has failed to do so.'" Schumacher, 2 F.3d at 1132 n.6 (quoting Massing, 926 F.2d at 1135). After conducting an extensive review of the legislative history behind the Vaccine Act, the Federal Circuit in Schumacher concluded that "it is clear that Congress intended the prohibitions surrounding the filing of petitions for compensation . . . to apply only to civil suits against vaccine manufacturers . . . [and] vaccine administrators." Id. at 1133; Easter, slip op. at 14 (quoting Schumacher).

In a case construing both Massing and Schumacher, the United States Court of Federal Claims in Klahn v. Secretary of the Department of Health & Human Services, 31 Fed. Cl. 382 (1994), held, pursuant to Schumacher, that the Vaccine Act was inapplicable to a claim against a doctor who did not administer the vaccine. Id. at 387–88; accord Easter, slip op. at 14 (citing Klahn). The court in Klahn distinguished Massing on multiple grounds. First, the court noted that Massing involved a civil action that had been instituted *prior* to the effective date of the Vaccine Act. Second, the court noted that the civil action had been resolved by settlement *prior* to the filing of the petition in Vaccine Court. Third, the court noted that the Vaccine Act provision at issue in Massing

was § 11(c), which governs the content of petitions, but the provision at issue in Schumacher was § 11(a), which governs the relationship between filing a civil action and filing a claim in Vaccine Court.

Thus, Klahn offers no support for Defendants' position. There is no evidence that Plaintiffs failed to properly file a petition with the Vaccine Court, that is, there is no evidence that Plaintiffs "previously collected an award or settlement of a civil action for damages for such vaccine-related injury or death" 42 U.S.C. § 300aa-11(c)(1)(E). Thus, Massing is inapplicable to this case. Regardless, the adequacy of Plaintiffs' petition in Vaccine Court is irrelevant to a determination of whether this Court has jurisdiction over Eli Lilly and Ortho-Clinical, Defendants who have conceded that they are not vaccine manufacturers. Notwithstanding any previous ruling from this Court that may have suggested a different result, this Court therefore now holds, consistent with the interpretation of the Vaccine Act as made in Schumacher, Klahn, Toussaint, and Easter, that Plaintiffs' claims against Defendants are not barred by the Vaccine Act because it is undisputed that these Defendants are not vaccine manufacturers. For these reasons, the Court will deny Defendants' Motions to Dismiss for lack of jurisdiction pursuant to Rule 12(b)(1). The Court will now discuss Eli Lilly's Motion to Dismiss pursuant to Rule 12(b)(6).

B. Eli Lilly's Motion to Dismiss

In its briefs and at the motion hearing, Eli Lilly contended that it is undisputed that it did not manufacture the specific thimerosal that was in the RhoGAM administered to Jane Doe. Eli Lilly therefore asserts that Plaintiffs cannot state a claim against it under North Carolina law. Plaintiffs conceded at the motion hearing that Eli Lilly did not manufacture the thimerosal contained in the RhoGAM. (Mot. Hr'g Tr. (stating that "with regard to Lilly, we don't argue that they

manufactured” the thimerosal).) Plaintiffs thus conceded in the motion hearing that Eli Lilly was not liable to Plaintiffs under the North Carolina Products Liability Act, North Carolina General Statutes section 99B-1 to 99B-11 because Eli Lilly did not manufacture the thimerosal.

1. Plaintiffs’ Claim that Eli Lilly Negligently Marketed, Licensed, and Designed Thimerosal

However, in Section C of their Complaint, Plaintiffs contend that even though Eli Lilly did not manufacture the thimerosal in question, Eli Lilly is still liable for “negligence in the marketing, licensing and design of Thimerosal.” (Compl. at 27.) In order to state a negligence claim under North Carolina law, Plaintiffs must properly allege that Eli Lilly (1) owed Minor Child Doe a legal duty, (2) Eli Lilly breached that duty by failing to exercise reasonable care, and (3) Eli Lilly’s breach of that duty was the proximate cause of Plaintiffs’ injuries. Goodman v. Wenco Foods, Inc., 333 N.C. 1, 18, 423 S.E.2d 444, 452 (1992). As the North Carolina Supreme Court reiterated in Hart v. Ivey, 332 N.C. 299, 420 S.E.2d 174 (1992), “[a]ctionable negligence is the failure to exercise that degree of care which a reasonable and prudent person would exercise under similar conditions. A defendant is liable for his negligence if the negligence is the proximate cause of injury to a person to whom the defendant is under a *duty* to use reasonable care.” Id. at 305, 420 S.E.2d at 177–78 (emphasis added).

Thus, Plaintiffs must first establish that Eli Lilly owed Minor Child Doe a duty to exercise reasonable care. In support of their case, Plaintiffs first rely upon Hart v. Ivey. In Hart, the North Carolina Supreme Court reiterated the bedrock principle of negligence law that “‘[t]he law imposes upon every person who enters upon an active course of conduct the positive duty to exercise ordinary care to protect others from harm, and calls a violation of that duty negligence.’” Id. at 305, 420 S.E.2d at 178 (alteration in original) (quoting Council v. Dickerson’s, Inc., 233 N.C. 472, 474,

64 S.E.2d 551, 553 (1951)).

Plaintiffs contend that Eli Lilly owed Minor Child Doe a duty, it breached that duty, and its breach of that duty was a proximate cause of Plaintiffs' damages. Eli Lilly responds that it is not the actual manufacturer of the thimerosal contained in the RhoGAM given to Jane Doe. Eli Lilly instead maintains that the actual manufacturer simply copied Eli Lilly's expired thimerosal patent. Eli Lilly thus contends that because it did not manufacture the thimerosal in question, it did not owe a duty to Plaintiffs. As stated above, Plaintiffs have conceded that Eli Lilly did not manufacture the thimerosal.

Although Plaintiffs assert that this Court should impose tort liability on Eli Lilly, Plaintiffs have cited no North Carolina case, and this Court can locate none, holding a defendant liable for failing to warn potential users of a product about the dangers of that product where the defendant did not manufacture the product but simply knew that other manufacturers were copying its expired patent. Plaintiffs concede that there are no North Carolina cases directly on point but contend that the principle enunciated by the North Carolina Supreme Court in Hart v. Ivey that "[t]he law imposes upon every person who enters upon an active course of conduct the positive duty to exercise ordinary care to protect others from harm, and calls a violation of that duty negligence" would apply to Eli Lilly in this case. Id. (alteration in original) (internal quotations omitted). In Hart, the supreme court held that the defendants, social hosts who served alcohol to their guests, "were under a duty to the people who travel on the public highways not to serve alcohol to an intoxicated individual who was known to be driving." Id. at 305, 420 S.E.2d at 178. The Court, however, finds that the facts of Hart are distinguishable from the facts of the present case. In accordance with Hart, the Court finds that if Eli Lilly had manufactured or licensed for manufacture

the thimerosal in the RhoGAM Jane Doe received, its “active course of conduct” would give rise to a duty to potential users of the thimerosal. Here, however, Eli Lilly did not enter into an active course of conduct to produce thimerosal for inclusion in the RhoGAM Jane Doe received. The Court therefore finds, consistent with Hart, that the North Carolina Supreme Court would not extend tort liability to Eli Lilly in this situation.

Plaintiffs also relies upon the case of James v. Charlotte-Mecklenburg Board of Education, 60 N.C. App. 642, 300 S.E.2d 21 (1983). In James, the plaintiff, on behalf of his minor daughter, sued his daughter’s schoolteacher for negligence when his daughter lost her vision after being hit in the eye with a pencil by a fellow student. The plaintiff claimed that the teacher was negligent because she left the children unsupervised in the classroom while she finished her lunch in the cafeteria. The question before the court of appeals, therefore, was “whether [the teacher] was under a duty to remain in her classroom at all times while her pupils were present in the class.” Id. at 645, 300 S.E.2d at 23.

The Court again finds, however, that James does not assist Plaintiffs. First, the court in James did not find the teacher liable. Second, the facts in James are much different than the facts in the present case. Third, a close reading of James indicates that there was no question that the teacher owed at least some duty of care to her students. The precise question in James was the extent of the duty the teacher owed to her students. In the cases relied upon by the court of appeals in James, there was no dispute that the defendants owed some duty of care to the plaintiffs; the question, as in James, was the extent of that duty. See Toone v. Adams, 262 N.C. 403, 407, 137 S.E.2d 132, 135 (1964) (holding that the contract between the plaintiff and the defendant created a legal duty on the defendant to exercise ordinary care to protect the plaintiff from harm); Foster

v. Winston-Salem Joint Venture, 303 N.C. 636, 638–39, 281 S.E.2d 36, 38 (1981) (holding that it was well-established that a defendant store owner owed a duty of care to the plaintiff invitee and its duty would in some cases extend to protecting the invitee from harm caused by third parties); cf. Moore v. Crumpton, 306 N.C. 618, 623, 295 S.E.2d 436, 440 (1982) (holding “that the parent of an unemancipated child may be held liable in damages for failing to exercise reasonable control over the child’s behavior if the parent had the ability and the opportunity to control the child and knew or should have known of the necessity for exercising such control”).

In the present case, there is no contractual or other special relationship between Plaintiffs and Eli Lilly upon which a duty could be based. Furthermore, even if Eli Lilly did owe Plaintiffs some duty of reasonable care based upon its course of conduct with respect to thimerosal, the Court finds that, under existing North Carolina law, Eli Lilly’s duty to Plaintiffs would not extend to warning Plaintiffs or other manufacturers who copied thimerosal about the alleged dangers of thimerosal. Plaintiffs have simply cited no case or authority indicating that the North Carolina Supreme Court would impose such a duty upon Eli Lilly.

Further supporting the Court’s conclusion that Eli Lilly does not owe a duty to Plaintiffs is the opinion of the Northern District of Georgia in a similar case brought against Eli Lilly under Georgia law. In Murphy v. Aventis Pasteur, Inc., 270 F. Supp. 2d 1368 (N.D. Ga. 2003), the district court dismissed the plaintiff’s complaint where the plaintiff alleged that Eli Lilly “failed to warn consumers of the alleged dangers of thimerosal.” Id. at 1376–77. The district court reasoned as follows:

The plaintiff has not directed the court to any authority expanding this duty beyond the manufacturer of the product in question. The chain of commerce that begins with the manufacturer and ends with the final consumer involves a series of special relationships. These special relationships provide a basis for the affirmative duty to

warn.

The duty proposed by the plaintiff does not arise from any special relationship. Instead, the plaintiff alleges the existence of an affirmative duty to warn which arises merely from being the developer, inventor, or patent holder of a product or design. The plaintiff reasons that Lilly, as the holder of the patent on thimerosal, knew that other companies would copy thimerosal when the patent expired. The plaintiff further reasons that such knowledge on the part of Lilly gave rise to an ongoing duty to warn the purchasers and recipients of such copied products manufactured by other companies. The plaintiff has not cited and the court has not found any authority supporting the existence of such a duty. Accordingly, the court concludes that no such duty exists under Georgia law. Thus, the plaintiff's negligence claim against Lilly is not cognizable under Georgia law and, as such, is due to be dismissed.

Id. at 1377. Likewise, this Court finds Plaintiffs's claim for "negligence in the marketing, licensing and design of Thimerosal" is not cognizable under North Carolina law. This claim is therefore dismissed.

2. Other Claims Against Eli Lilly

During the motion hearing, counsel for Plaintiffs and Eli Lilly focused on Plaintiffs' claim against Eli Lilly for "negligence in the marketing, licensing, and design of Thimerosal," but failed to address the viability of the other twelve claims (the claims in Section A and Section D of the Complaint) that Plaintiffs have also asserted against Eli Lilly. The Court must therefore determine whether, based upon Plaintiffs' concession that Eli Lilly did not manufacture the thimerosal in question, the claims in Section A and Section D of the Complaint are still viable against Eli Lilly.

a. Section A Claims Against Eli Lilly

In Section A of the Complaint, Plaintiffs asserted eight claims solely against "Product Defendants," that is, Defendants who were alleged to have manufactured RhoGAM or thimerosal. These claims included the following: (1) negligence, (2) negligent failure to warn, (3) inadequate design or formulation, (4) breach of express warranty of merchantability, (5) breach of implied

warranties, (6) negligent misrepresentation, (7) intentional misrepresentation and fraud, and (8) violation of the North Carolina Unfair and Deceptive Trade Practices Act. As discussed more fully above, however, Plaintiffs have now conceded that Eli Lilly did not manufacture the thimerosal in the RhoGAM that Jane Doe received. Thus, the Court finds that Plaintiffs' subsequent concession in the motion hearing that Eli Lilly did not manufacture the thimerosal in question is fundamentally inconsistent with the allegations of Plaintiffs' Complaint. In other words, Plaintiffs asserted their first eight claims against Eli Lilly as a "Product Defendant," alleging that Eli Lilly manufactured either thimerosal or RhoGAM, and now Plaintiffs have conceded that Eli Lilly did neither. Furthermore, during the motion hearing Plaintiffs' counsel only addressed Plaintiffs' claim against Eli Lilly for negligence in the marketing, licensing, and design of thimerosal. There was no mention of Plaintiffs' claims for breach of warranty, fraud, or unfair and deceptive trade practices, nor was there any mention of Plaintiffs' other negligence-based claims. In summary, therefore, the Court finds that Plaintiffs' concession that Eli Lilly did not manufacture the thimerosal in the RhoGAM is in effect a withdrawal of Plaintiffs' Section A Claims against Eli Lilly. Accordingly, these eight claims against Eli Lilly are dismissed without prejudice.

b. Section D Claims Against Eli Lilly

In Section D of the Complaint, Plaintiffs asserted the following four claims against "All Defendants": (1) negligent infliction of emotional distress, (2) gross negligence, (3) punitive damages, and (4) loss of parental consortium. Although not specifically addressed by the parties at the motion hearing, the Court finds that Plaintiffs still seek to pursue these claims against Eli Lilly even in light of Plaintiffs' concession that Eli Lilly did not manufacture the thimerosal included in the RhoGAM. The Court will therefore discuss whether these claims are still viable against Eli Lilly.

(1) Negligent Infliction of Emotional Distress and Gross Negligence

Both Plaintiffs' claims for (1) negligent infliction of emotion distress and (2) gross negligence, like Plaintiffs' claim for negligent licensing, marketing, and design, are apparently based upon Plaintiffs' contention that Eli Lilly breached its duty to warn Plaintiffs about the dangers of thimerosal. The Court, however, has previously dismissed Plaintiffs' claim for negligent licensing, marketing, and design because North Carolina law does not support Plaintiffs' contention that Eli Lilly owes a duty to warn even though it did not actually manufacture or license the thimerosal included in the RhoGAM. Accordingly, Plaintiffs' claims for negligent infliction of emotional distress and gross negligence must also be dismissed because Plaintiffs have failed to adequately allege any negligent conduct by Eli Lilly against Plaintiffs. See Murphy v. Aventis Pasteur, Inc., 270 F. Supp. 2d 1368, 1377–78 (N.D. Ga. 2003) (dismissing the plaintiffs' negligent-infliction-of-emotional-distress claim against Eli Lilly because it had already dismissed the plaintiffs' negligent-failure-to-warn claim).

(2) Loss of Consortium

Plaintiffs John and Jane Doe also bring a joint claim for loss of consortium based upon Eli Lilly's wrongful conduct. Although styled as a claim for "loss of consortium," Plaintiffs actually request relief for loss of consortium, loss of services, and medical expenses incurred on behalf of Minor Child Doe. (Compl. ¶ 134.) As this Court recently held in Laughter v. Aventis Pasteur, Inc., however, in North Carolina "[t]he relation of parent and child supports no legal right similar to that of consortium." 291 F. Supp. 2d 406, 413 (M.D.N.C. 2003) (alteration in original) (quoting Edwards v. Edwards, 43 N.C. App. 296, 302, 259 S.E.2d 11, 15 (1979)). North Carolina does, however, recognize an independent cause of action for a parent when a minor child is injured

through the negligence of another. See Brown v. Lyons, 93 N.C. App. 453, 458, 378 S.E.2d 243, 246 (1989) (citing Flippin v. Jarrell, 301 N.C. 108, 120, 270 S.E.2d 482, 490 (1980)). The parent may maintain “a claim . . . for loss of services during the child’s minority and for medical expenses to treat the injury.” Id. (citing Flippin v. Jarrell, 301 N.C. 108, 120, 270 S.E.2d 482, 490 (1980)).

Thus, to the extent that John and Jane Doe pursue a claim for loss of services and for medical expenses incurred on behalf of Minor Child Doe, those claims are recognized under North Carolina law. However, such claims are only viable if the defendant committed some wrongful act contributing to the minor child’s injury. In this case, the Court has dismissed all of Plaintiffs’ claims for negligence, breach of warranty, fraud, and unfair and deceptive trade practices either because these claims are not recognized under North Carolina law or because Plaintiffs have abandoned these claims. Plaintiffs John and Jane Doe can therefore point to no wrongful conduct by Eli Lilly for which this Court can provide relief. Accordingly, Plaintiffs’ claims for loss of services and medical expenses against Eli Lilly are hereby dismissed.

(3) Punitive Damages

Although Section D of Plaintiffs’ Complaint contains a separate “claim” for punitive damages, Plaintiffs’ request for punitive damages is not a cause of action standing alone but is in fact derivative of Plaintiffs’ other claims. Staley v. Lingerfelt, 134 N.C. App. 294, 298, 517 S.E.2d 392, 395 (1999) (citing Holley v. Hercules, Inc., 86 N.C. App. 624, 359 S.E.2d 47 (1987)). Accordingly, because the Court has dismissed all of Plaintiffs’ actual causes of action against Eli Lilly, the Court must also dismiss Plaintiffs’ “claim” against Eli Lilly for punitive damages.

In summary therefore, the Court grants Eli Lilly’s Motion to Dismiss pursuant to Rule 12(b)(6) because Plaintiffs have failed to state viable claims against Eli Lilly. Accordingly, Plaintiffs’

claims against Eli Lilly are dismissed in their entirety. As such, to the extent that Eli Lilly also contended that it should be dismissed pursuant to Rule 12(b)(7) or that Plaintiffs' claims against it should be stayed, these contentions are now moot. The Court will therefore only address whether it should grant Ortho-Clinical's Motion to Dismiss pursuant to Rule 12(b)(7) or Ortho-Clinical's alternative Motion to Stay.

C. Ortho-Clinical's Motion to Dismiss or Stay

As an alternative to dismissing Plaintiffs' claims as being barred by the Vaccine Act, Defendant Ortho-Clinical moves this Court to dismiss Plaintiffs' claims under Federal Rule of Civil Procedure 12(b)(7) for failure to join indispensable parties (i.e., the vaccine manufacturers) under Rule 19. Ortho-Clinical also moves the Court in the alternative to stay Plaintiffs' claims during the pendency of Plaintiffs' claims in the Vaccine Court. The Court will address Ortho-Clinical's contentions in turn.

1. Ortho-Clinical's Motion to Dismiss for Failure to Join Indispensable Parties

Federal Rule of Civil Procedure 19(a) requires that necessary parties be joined to an action.

Fed. R. Civ. P. 19(a). A party is "necessary" under Rule 19(a)

if (1) in the person's absence complete relief cannot be accorded among those already parties, or (2) the person claims an interest relating to the subject of the action and is so situated that the disposition of the action in the person's absence may (i) as a practical matter impair or impede the person's ability to protect that interest or (ii) leave any of the persons already parties subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations by reason of the claimed interest. . . .

Id. If a necessary party cannot be joined, the Court must determine whether that party is indispensable; if it is, the Court must dismiss the action. To determine if a party is indispensable under Rule 19(b), the Court must consider the following factors:

first, to what extent a judgment rendered in the person's absence might be prejudicial to the person or those already parties; second, the extent to which, by protective provisions in the judgment, by the shaping of relief, or other measures, the prejudice can be lessened or avoided; third, whether a judgment rendered in the person's absence will be adequate; fourth, whether the plaintiff will have an adequate remedy if the action is dismissed for nonjoinder.

Fed. R. Civ. P. 19(b). The Fourth Circuit Court of Appeals has held that “[c]ourts are loath to dismiss cases based on nonjoinder of a party, so dismissal will be ordered only when the resulting defect cannot be remedied and prejudice or inefficiency will certainly result.” Owens-Illinois, Inc. v. Meade, 186 F.3d 435, 441 (4th Cir. 1999).

a. Whether the Vaccine Manufacturers Are Necessary Parties

Ortho-Clinical does not contend that in the absence of the Vaccine manufacturers “complete relief cannot be accorded among those already parties” Fed. R. Civ. P. 19(a)(1). Instead, Ortho-Clinical contends, pursuant to Rule 19(a)(2), that “[t]he vaccine manufacturers are necessary parties to this action because permitting both this action and the plaintiffs’ claims before the Vaccine Court to continue simultaneously will ‘likely subject all [of] the parties to conflicting legal obligations in a manner prohibited by Rule 19(a)(2)(ii).’ ” (Mem. Supp. Ortho-Clinical’s Mot. Dismiss or Stay at 13 (quoting Owens-Illinois, 186 F.3d at 441).) Ortho-Clinical further contends that “[i]n both forums, the Courts will be asked to determine the same causal issue as to thimerosal and neurodevelopmental disorders. The potential for inconsistent judgments is a well recognized ground for finding a non-party necessary.” (Id. (citing Owens-Illinois, 186 F.3d at 441).)

Ortho-Clinical’s arguments, however, misconstrue Rule 19 and the function of the Vaccine Court. Rule 19(a)(2)(ii) states that a party is necessary only if nonjoinder would “leave any of the persons *already* parties subject to a substantial risk of incurring double, multiple, or otherwise inconsistent obligations by reason of the claimed interest.” Rule 19(a)(2)(ii) (emphasis added).

Ortho-Clinical fails to explain how it could incur a “double, multiple, or otherwise inconsistent obligation” if this Court allows Plaintiffs’ claims against it to proceed. Plaintiffs seek only one recovery from Ortho-Clinical for injuries that Plaintiffs allege were caused by the thimerosal in RhoGAM. Furthermore, there is no reason why the nonjoined parties (i.e., the vaccine manufacturers) would seek a recovery from Ortho-Clinical for Plaintiffs’ RhoGAM-related injuries. Thus, there does not appear to be a risk that Ortho-Clinical would be subject to double or multiple obligations.

Ortho-Clinical further seems to contend, however, that it would be subjected to an inconsistent obligation if the special master fails to find a causal connection between thimerosal and neurodevelopmental disorders but a jury in this Court comes to the opposite conclusion. This argument is without merit. The Vaccine Court’s ruling on the causal connection between thimerosal and neurodevelopmental disorders has no bearing on this Court’s determination of that issue with respect to Ortho-Clinical. As this Court has discussed more fully above, the Vaccine Court lacks jurisdiction over Plaintiffs’ claims against Ortho-Clinical; thus, whatever judgment the Vaccine Court renders would bind only the United States Government, not Ortho-Clinical. In summary therefore, the Court finds that, based on the evidence and arguments currently before the Court, the vaccine manufacturers are not *necessary* parties to this action.

b. Whether the Vaccine Manufacturers Are Indispensable Parties

Even if the Court were to find the vaccine manufacturers to be necessary parties under Rule 19(a), the Court would still not find them to be indispensable parties under Rule 19(b) such that failure to join them to this action would require dismissal of Plaintiffs’ claims. Ortho-Clinical has simply offered no support for its position that “to proceed with this case without the vaccine

manufacturers would prejudice [Ortho-Clinical] in defending plaintiffs' claim that the minor plaintiffs [sic] exposure to RhoGAM was the cause of her neuro-developmental disorder." (Mem. Supp. Ortho-Clinical's Mot. Dismiss or Stay at 14.)

The Court finds, moreover, that a ruling by this Court that the vaccine manufacturers are indispensable parties under Rule 19(b) would actually prejudice Plaintiffs. Such a ruling could subject Plaintiffs to the very real possibility of obtaining no relief against Ortho-Clinical based on their allegations that RhoGAM caused Minor Child Doe's neurodevelopmental disorders. The Court notes that Ortho-Clinical's arguments seem to contemplate that Minor Child Doe (through her parents) will ultimately file civil actions against the vaccine manufacturers in this Court, and until she does, all claims against Ortho-Clinical must be dismissed. However, Minor Child Doe may elect not to ever file civil actions against any vaccine manufacturers if she prevails in Vaccine Court. As discussed above, if Minor Child Doe were to prevail in Vaccine Court on her significant-aggravation claim and elected to accept the remedy provided by the Vaccine Court, she would be unable to file a civil action against the vaccine manufacturers in this Court. 42 U.S.C. § 300aa-11(a)(3). Under Ortho-Clinical's rationale, however, if the vaccine defendants were determined to be indispensable, Minor Child Doe's inability to file a civil action against the vaccine manufacturers in this Court would also prevent Minor Child Doe from pursuing her separate claims for relief against Ortho-Clinical. Minor Child Doe would therefore either be left with only a partial recovery in Vaccine Court or would be forced to opt out of the Vaccine Court's ruling and then pursue claims in this Court against both Ortho-Clinical and the vaccine manufacturers. Thus, a finding by this Court that the vaccine manufacturers are indispensable parties could result in extreme prejudice to Plaintiffs. First, it could deny Minor Child Doe the right to recover for her RhoGAM-related injuries if she

also wished to accept the Vaccine Court's ruling with respect to her vaccine-related claims for significant aggravation. Second, it could effectively deny Minor Child Doe her right to obtain relief in the Vaccine Court if she also wished to obtain relief in this Court for her RhoGAM-caused injuries. Furthermore, such a finding would circumvent Congress' intent in enacting the Vaccine Act because it would in effect require plaintiffs to pursue civil actions (as opposed to accepting the Vaccine Court's award) against vaccine manufacturers in order to obtain full recovery for their injuries.

Thus, the Court finds that while the vaccine manufacturers, if they were subject to suit in this Court, would likely be permissive parties under Rule 20, they are not necessary or indispensable parties pursuant to Rule 19. As the First Circuit Court of Appeals has held,

While it is true that the Federal Rules encourage the joinder of parties where such joinder would appear to avoid multiple actions or unnecessary delay and expense, this practice should not penalize bona fide litigants who have a valid cause of action, choose the forum which they think proper, and ask for specific relief.

Field v. Volkswagenwerk AG, 626 F.2d 293, 302 (1st Cir. 1980). In conclusion, the Court finds that, based upon the arguments and allegations before the Court at this time, the vaccine manufacturers are neither necessary nor indispensable parties under Rule 19. The Court will therefore deny Ortho-Clinical's Motion to Dismiss pursuant to Rule 12(a)(7) without prejudice to Ortho-Clinical's right to renew this motion prior to trial.

2. Ortho-Clinical's Motion to Stay

In the alternative to dismissal, Ortho-Clinical moves this Court to stay Plaintiffs' claims against it pending the outcome of Plaintiffs' petition in Vaccine Court. The Court has the inherent power to stay proceedings to achieve equity and to ensure the efficient management of its docket. Williford v. Armstrong World Indus., Inc., 715 F.2d 124, 127 (4th Cir. 1983) (citing Landis v. N.

Am. Co., 299 U.S. 248, 254–55, 57 S. Ct. 163, 165–66, 81 L. Ed. 153 (1936)). Before issuing a stay, the Court “must weigh competing interests [of the parties] and maintain an even balance.” Id. (internal quotations omitted). “The party seeking a stay must justify it by clear and convincing circumstances outweighing potential harm to the party against whom it is operative.” Id.

Ortho-Clinical makes the following arguments in support of its Motion to Stay: (1) the Vaccine Court is deciding the same issue that this Court is being called upon to decide; (2) Plaintiffs are attempting to recover for the same injuries in Vaccine Court as they are in this Court; (3) the vaccine manufacturers are necessary and indispensable parties to this action; (4) Ortho-Clinical will be prejudiced if the Court allows the case to proceed without the vaccine manufacturers; (5) allowing the case to continue would be inconsistent with the Vaccine Act’s goal of minimizing litigation costs; and (6) allowing the case to continue would be an inefficient and costly use of this Court’s resources.

With respect to Ortho-Clinical’s first, second, and third contentions, this Court has rejected these same arguments with respect to Ortho-Clinical’s Motions to Dismiss pursuant to Rules 12(b)(1) and 12(b)(7). With respect to arguments one and two, the Vaccine Court is being asked to decide only whether Minor Child Doe’s neurodevelopmental disorder was significantly aggravated by the thimerosal in the vaccines. While that review will encompass any pre-existing condition Minor Child Doe had prior to receiving the vaccines, the Vaccine Court’s determination of that issue will not be binding on this Court’s consideration of the effect of RhoGAM on Minor Child Doe’s condition. Plaintiffs’ theory of recovery in Vaccine Court is that the vaccines significantly aggravated Minor Child Doe’s pre-existing condition, which Plaintiffs’ allege was caused by the thimerosal in RhoGAM. Thus, Plaintiffs are not seeking a double recovery, but a complete recovery.

With respect to Ortho-Clinical's third contention, the Court has determined that Ortho-Clinical has failed to show that the vaccine manufacturers are necessary and indispensable parties under Rule 19. With respect to Ortho-Clinical's fourth contention, which is closely tied to its third contention, Ortho-Clinical has simply offered no support for its assertion that the absence of the vaccine manufacturers would result in prejudice to it. Ortho-Clinical has failed to explain why, even without the vaccine manufacturers as defendants, it would be unable to adequately defend itself against Plaintiffs' claims. Presumably, Ortho-Clinical is concerned that it could be found liable in this Court for the full extent of Minor Child Doe's injuries, even though part of those injuries might be attributable to the thimerosal in the vaccines Minor Child Doe received. However, Ortho-Clinical has failed to explain to this Court why it would be unable to present to a jury evidence and arguments that vaccines caused or aggravated Minor Child Doe's injuries. It is thus unclear to the Court why Ortho-Clinical could not obtain and proffer medical evidence about the vaccines Minor Child Doe received, the amount of the thimerosal in those vaccines, when those vaccines were administered to Minor Child Doe, and the effect those vaccines may have had on Minor Child Doe's neurological development. Thus, at least at this stage of the proceedings, Ortho-Clinical has failed to satisfy its burden to show that a stay is necessary to prevent it from being prejudiced.

Ortho-Clinical's fifth contention is that allowing Plaintiffs' claims to proceed against Ortho-Clinical " 'would be wholly inconsistent with Congress's goal of minimizing litigation costs'" (Mem. Supp. Ortho-Clinical's Mot. Dismiss or Stay at 10 (quoting Liu v. Aventis Pasteur, Inc., 219 F. Supp. 2d 762, 767 (W.D. Tex. 2002))). However, a close review of the legislative history surrounding the enactment of the Vaccine Act does not support Ortho-Clinical's position that one of the goals of the Vaccine Act is to minimize litigation costs for non-vaccine manufacturers. In

describing the purpose of the Vaccine Act, the House of Representatives noted, in pertinent part, as follows:

Currently, vaccine-injured persons can seek recovery for their damages only through the civil tort system or through a settlement arrangement with the *vaccine manufacturer*. Over time, neither approach has proven satisfactory. Lawsuits and settlement negotiations can take months and even years to complete. Transaction costs—including attorneys' fees and court payments—are high. And in the end, no recovery may be available. Yet futures have been destroyed and mounting expenses must be met.

This approach has also been ineffective for the *manufacturers of childhood vaccines*. This has become especially true in more recent years as the number of lawsuits—particularly those concerning the DPT vaccine—has increased. . . . Manufacturers have become concerned not only with the problems of time and expense, but with the issue of the availability of affordable product liability insurance that is used to cover losses related to vaccine injury cases. Whether current problems with liability insurance arise from a crisis in the tort system or from a particularly bad downturn in the business cycle of the insurance industry has been and remains a matter of great controversy. Nevertheless, there is little doubt that *vaccine manufacturers* face great difficulty in obtaining insurance. This lack of insurance was the stated reason for one manufacturer to withdraw temporarily from the vaccine market in 1984. Others have suggested that they may follow a similar course of action. This factor, coupled with the possibility that vaccine-injured persons may recover substantial awards in tort claims, has prompted manufacturers to question their continued participation in the *vaccine market*.

The loss of any of the existing *manufacturers of childhood vaccines* at this time could create a genuine public health hazard in this country. Currently, there is only one manufacturer of the polio vaccine, one manufacturer of the measles, mumps, rubella (MMR) vaccine, and two manufacturers of the DPT vaccine. Two States, Michigan and Massachusetts, produce their own DPT vaccine. Despite Congressional support, Federal vaccine stockpiles maintained by the Centers for Disease Control (CDC) have never reached CDC's recommended level of six-months' supply. Thus, the withdrawal of even a single manufacturer would present the very real possibility of vaccine shortages, and, in turn, increasing numbers of unimmunized children, and, perhaps, a resurgence of preventable diseases.

. . . .

Thus, two overriding concerns have led to the development of this legislation: (a) the inadequacy—from both the perspective of vaccine-injured persons as well as vaccine manufacturers—of the current approach to compensating those who have

been damaged by a vaccine; and (b) the instability and unpredictability of the *childhood vaccine market*.

H.R. Rep. 99-908, at 6–7 (1986), reprinted in 1986 U.S.C.C.A.N. 6344, 6347–48.

Thus, the legislative history of the Vaccine Act does not support Ortho-Clinical's position that one of the purposes of the Vaccine Act is to minimize litigation costs for non-vaccine manufacturers. However, in Liu v. Aventis Pasteur, Inc., 219 F. Supp. 2d 762 (W.D. Tex. 2002), the district court dismissed without prejudice the minor plaintiff's claims against the non-vaccine manufacturers, reasoning that allowing discovery to proceed against those manufacturers "would be wholly inconsistent with Congress's goal of minimizing litigation costs." Id. at 767. However, in Liu, the non-vaccine manufacturers were actually alleged to be manufacturers of the thimerosal contained in the vaccines. Thus, prohibiting discovery against such manufacturers could arguably be consistent with Congress' goal of ensuring the availability of vaccines. In the present case, however, Plaintiffs seek to proceed against the manufacturer of RhoGAM, which is neither a vaccine nor a component of a vaccine. The Court therefore finds that Congress' goal of minimizing litigation costs for vaccine manufacturers does not support a stay of Plaintiffs' claims against Ortho-Clinical.

Finally, Ortho-Clinical seeks a stay based upon Judge Flanagan's decision in Doe 3, in which Judge Flanagan found that "[c]ontinued litigation in the Vaccine Court necessarily will require consideration of the intertwined issue in this case of exposure to thimerosal through the immune globulin product RhoGAM." Doe 3 v. Ortho-Clinical Diagnostics, Inc., No. 7:03-CV-138-FL(1), slip op. (E.D.N.C. Jan. 7, 2004), recons. denied, No. 7:03-CV-138-FL(1), slip op. at 6 (E.D.N.C. Mar. 17, 2004). Accordingly, Judge Flanagan found that "[u]ndoubtedly, discovery will be undertaken on this, and a number of experts will be retained in the context of evaluating the minor

plaintiff's claims in Vaccine Court. A parallel inquiry [in federal court] on a different timetable is duplicative, expensive, and wasteful of resources." Id. Thus, Judge Flanagan concluded that "a stay in this instance would economize the court's time, and that of counsel and the litigants, avoid the waste of duplicative fact-finding, and promot[e] consistency of ruling." Id. at 5.

This Court, however, finds that Ortho-Clinical has not carried its burden to demonstrate that a stay is warranted in this case. Ortho-Clinical has simply failed to show how it would be a waste of this Court's or the parties' resources to allow Plaintiffs' RhoGAM claims to proceed against Ortho-Clinical. While the Vaccine Court may in fact be assessing the extent to which thimerosal in RhoGAM impacted Minor Child Doe's neurological development, the Vaccine Court's inquiry is independent of this Court's inquiry. Ortho-Clinical has offered no evidence or argument that the special master has ordered it to submit to discovery in the Vaccine Court with respect to the effect of RhoGAM on children's neurological development. Thus, allowing Plaintiffs to proceed with discovery against Ortho-Clinical would not be duplicative or wasteful. In fact, it appears that such discovery will be necessary regardless of the resolution of Plaintiffs' claims in Vaccine Court.

Furthermore, to the extent that Ortho-Clinical argues that allowing the Vaccine Court proceedings to run their course before allowing Plaintiffs to proceed with their case against Ortho-Clinical "promot[es] consistency of ruling," the Court is unpersuaded by this argument. As previously discussed, the Vaccine Court's resolution of Minor Child Doe's Vaccine Court petition does not bind this Court. See Doe 3, No. 7:03-CV-138FL(1), slip op. at 6 (E.D.N.C. Mar. 17, 2004) (holding that "[t]he instant case is in no way barred or bound by [the Vaccine Court's] decision"). In fact, even if Plaintiffs ultimately do bring the vaccine manufacturers into this case, the Vaccine Act provides that "any finding of fact or conclusion of law of the United States Court of Federal

Claims or a special master in a proceeding on a petition filed under section 300aa-11 of this title and the final judgment of the United States Court of Federal Claims and subsequent appellate review on such a petition shall not be admissible.” 42 U.S.C. § 300aa-23(e).

In conclusion, therefore, the Court finds that Plaintiffs’ claims against Ortho-Clinical may proceed, at least for purposes of discovery on the issues related to RhoGAM. Ortho-Clinical has simply failed to show how allowing this case to proceed against it would result in any prejudice to it, especially during the pretrial stage of these proceedings. The Court notes, however, that events in the Vaccine Court or developments during the discovery process may warrant a stay. For example, if the Vaccine Court rules against Plaintiffs or Plaintiffs decide to opt out of the Vaccine Court, it may be appropriate for the Court to enter a limited stay to allow all of Plaintiffs’ claims against both Ortho-Clinical and the vaccine manufacturers to be consolidated into one civil action and be tried together in this Court. Accordingly, the Court will deny Ortho-Clinical’s Motion to Stay without prejudice to Ortho-Clinical’s right to refile its Motion if additional developments or information show that allowing Plaintiffs’ claims against Ortho-Clinical to proceed would either prejudice Ortho-Clinical or waste this Court’s time.

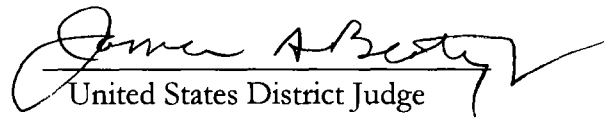
IV. CONCLUSION

For the foregoing reasons, therefore, this Court will deny Eli Lilly’s and Ortho-Clinical’s Motions to Dismiss pursuant to Rule 12(b)(1). The Court will grant Defendant Eli Lilly’s Motion to Dismiss pursuant to Rule 12(b)(6). Accordingly, to the extent that Eli Lilly brings any other Motions, these Motions are denied as moot. Furthermore, the Court will deny Ortho-Clinical’s Motion to Dismiss pursuant to Rule 12(b)(7), as well as Ortho-Clinical’s alternative Motion to Stay.

An Order and Judgment consistent with this Memorandum Opinion shall be filed

contemporaneously herewith.

This, the 3 day of September, 2004.


United States District Judge